K024111

JUN 10 2003

510K Summary of Safety and Effectiveness

Astra Tech Fixture OsseoSpeed
Astra Tech Fixture MicroMacro (new indication)

1. Sponsor Name:

   Astra Tech, Inc.
   430 Bedford St, Suite 100
   Lexington, MA 02240

2. Device Name

   Proprietary Names:

   Astra Tech Implants – Dental System Fixture OsseoSpeed
   Astra Tech Implants – Dental System Fixture MicroMacro (new indication)

   Common Name: Dental Implant

   Classification name: Endosseous Dental Implant (21 CFR 872.3640)

3. Identification of Legally Marketed Device

   The Fixture OsseoSpeed is substantially similar in intended use, material, and design when compared to implants previously cleared via Astra Tech's 510(k) Numbers K931767, K990304, and K991053. The Fixture OsseoSpeed is considered substantially equivalent to components previously cleared under these 510(k)'s.

   The Fixture MicroMacro is a legally marketed device (K991053) that has previously been found to be substantially equivalent to fixtures covered in Astra Tech 510(k) Number K931767. This 510(k) revises its intended use to include one stage surgical procedure and immediate loading situations under conditions previously approved for other Astra Tech fixtures under K002513 and K012965, respectively.

   The abutments used with the Fixture OsseoSpeed are equivalent in intended purpose, material, and design compared with the standard abutments cleared via K931767, K974738, and K980698.

4. Device Description

The Fixture OsseoSpeed is a root-form threaded dental implant made of Grade 4 titanium. The implant is produced by machining process, followed by grit blasting and cleaning. It is available in diameters 3.5, 4.0, 4.5 and 5.0 mm, and lengths from 8mm to 19mm. It is placed via one or two stage surgery and the functional loading can be from immediate to delayed.

Fixture MicroMacro is of similar design and construction and is available in diameters 3.5 and 4.0mm, and lengths from 8mm to 19mm.

5. Intended Use

The Fixture OsseoSpeed and Fixture MicroMacro are intended for endosseous implantation in the mandible and maxilla supporting single-tooth replacements, partial and total fixed/fixed detachable bridges and overdentures. One or two stage surgical procedure can be used. When using the one stage surgical protocol, immediate loading may be applied in the anterior mandibular region (between the mental foramina) if at least four implants are splinted with a bar, or other continuous suprastructure.

6. Comparison of Technological Characteristics

Substantial equivalence of the Fixture OsseoSpeed is based on:

1. Design similarities between the proposed Fixture OsseoSpeed and the currently marketed Fixtures within the Astra Tech Dental System.

2. Performance testing. The proposed and currently marketed devices are very similar in terms of size, materials of construction, performance characteristics, and basic design.

The differences have no effects on the performance or safety of the Fixture OsseoSpeed as evaluated in the performance testing. The same types of safety and effectiveness characteristics are raised with each of the devices. The changes described above do not raise new questions related to safety or efficacy of the implant.

In summary, the Fixture OsseoSpeed described in this submission is substantially equivalent to the predicate devices listed, which provide the same or similar functions, as well as design and technological characteristics. Similarly, the immediate loading claim for Fixture MicroMacro is based upon its substantial equivalence with other fixtures bearing this claim. The intended use, statement of indications, technological characteristics and testing for the Fixture OsseoSpeed and Fixture MicroMacro support the concept of substantial equivalence.

7. Performance Testing

Laboratory testing was conducted to determine device functionality and conformance to design input requirements. The immediate loading claims for Fixture Osseospeed and Fixture MicroMacro were supported by clinical data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2003

Astra Tech,, Incorporated
C/O Mr. Bruce R. Manning
New England BioMedical Research, Incorporated
96 West Main Street
P.O. Box 809
Northborough, Massachusetts 01532

Re: K024111
Trade/Device Name: Astra Tech Implants- Dental System Fixture OsseoSpeed
Astra Tech Implants- Dental System Fixture MicroMarco
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: March 13, 2003
Received: March 14, 2003

Dear Mr. Manning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3

510(k) Number (if known): K024111

Device Name:

Astra Tech Implants – Dental System Fixture OsseoSpeed
Astra Tech Implants – Dental System Fixture MicroMacro (new indication)

Indications For Use:

Fixture OsseoSpeed and Fixture MicroMacro are intended for endosseous implantation in the mandible and maxilla supporting single-tooth replacements, partial and total fixed/fixed detachable bridges and overdentures. One or two stage surgical procedure can be used. When using the one stage surgical protocol, immediate loading may be applied in the anterior mandibular region (between the mental foramina) if at least four implants are splinted with a bar, or other continuous suprastructure.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

Kevin Mulcahy for MSP

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K024111